

**UNITED STATES DISTRICT COURT
DISTRICT OF MINNESOTA**

IN RE: Bair Hugger Forced Air Warming
Products Liability Litigation

MDL No. 2666 (JNE/FLN)

This Document Relates to
ALL ACTIONS

**DEFENDANTS' RESPONSE TO PLAINTIFFS' OBJECTION TO RULING OF
MAGISTRATE JUDGE ON PUNITIVE DAMAGES**

Judge Noel correctly concluded that Plaintiffs' proposed allegations were legally inadequate to support a claim for punitive damages, and he correctly denied leave to amend. Plaintiffs did not allege facts in their proposed amended Master Complaint that would support a reasonable inference that Defendants deliberately disregarded a high probability of injury to patients. On the contrary – Plaintiffs based their proposed claim on a series of studies that all expressly *disclaim* any conclusion that the Bair Hugger system causes surgical site infections. Also, unlike other cases where plaintiffs were permitted to amend to seek punitive damages, Plaintiffs never identify (nor could they) any regulatory action, doctor report, or corporate admission supporting a reasonable inference that Defendants deliberately disregarded patient safety. As Judge Leary says in his August 18 order denying Plaintiffs' same motion for the Ramsey County cases, Plaintiffs "cannot spin straw into gold." (Declaration of Benjamin W. Hulse ("Hulse Decl."), Ex. A, Ramsey County Order ¶ 32.)

This Court may overrule Plaintiffs’ objection to Judge Noel’s order on either of two alternative grounds. The Court may concur with Judge Noel’s conclusion that Plaintiffs’ motion is governed exclusively by Rule 15, and that Plaintiffs have failed to plead facts sufficient to meet the substantive legal standard for seeking punitive damages under state law. Or the Court may overrule Plaintiffs’ objection on the alternative grounds that Plaintiffs failed to satisfy their evidentiary burden under Minn. Stat. § 549.191, for the reasons discussed in Judge Leary’s order. This Court can conclude, under the standard set forth in Justice Stevens’ concurrence in *Shady Grove*, that there is no conflict between Section 549.191 and the plain language of Rule 15(a)(2). The rules can peacefully coexist, and “justice requires” that Section 549.191’s requirements be applied to Plaintiffs’ motion just as they would apply if Plaintiffs had pursued their claims in Minnesota state court. As explained in Judge Leary’s order, Plaintiffs’ mishmash of snippets from various internal corporate documents, like their assemblage of scientific studies that disclaim causation, “falls far short” of the kind of evidence needed to pursue punitive damages. (Hulse Decl., Ex. A, Ramsey County Order ¶ 35.) *See also Berczyk v. Emerson Tool Co.*, 291 F. Supp. 2d 1004, 1016 (D. Minn. 2003) (“Of course, we are mindful that, with snippets from one document, when appended to another, some apparitions seem vaguely visible, but we must be presented, here, not with nebulous shadows, but with a requisite showing undergirded by clear and convincing evidence.”).

On either of these grounds, this Court should overrule Plaintiffs’ objection to Judge Noel’s order on punitive damages. Plaintiffs’ allegations in their proposed amended

Master Complaint are futile, and their evidentiary proffer is insufficient to make out a *prima face* case for punitive damages under applicable state law.

DISCUSSION

I. JUDGE NOEL CORRECTLY CONCLUDED THAT PLAINTIFFS DID NOT PLEAD FACTS SUFFICIENT TO SUPPORT A PLAUSIBLE CLAIM FOR PUNITIVE DAMAGES UNDER THE BELLWETHER STATES' LAWS.

A. Plaintiffs Do Not Challenge Judge Noel's Analysis of the Punitive Damages Standard.

Plaintiffs do not dispute the following elements of Judge Noel's analysis:

First, Plaintiffs concede that there is no actual conflict between Minnesota's substantive law of punitive damages and the substantive punitive damages laws of the states where the federal bellwether plaintiffs' claims arose (Wisconsin, Florida, Idaho, and South Carolina). (Order at 11.)

Second, Plaintiffs concede that, under Minnesota's punitive damages standard, Plaintiffs' allegations must support the reasonable inference that Defendants acted with deliberate disregard for the rights and safety of others. Specifically, Plaintiffs must allege facts to show that Defendants had "knowledge of facts or intentionally disregard[ed] facts that create a high probability of injury to rights and safety and (1) deliberately proceeds to act in conscious or intentional disregard of the high probability of injury to the rights or safety of others; or (2) deliberately proceeds to act with indifference to the high probability of injury to the rights or safety of others." ((*Id.* at 11-12), quoting Minn. Stat. § 549.20.) Notably, the standard is not merely (as Plaintiffs would have it) knowledge of an "increased risk" of injury – it is deliberate disregard for a *high probability of injury*.

And third, allegations of negligent acts are not sufficient to assert a claim for punitive damages. (Order at 17, *citing Admiral Merchs. Mot. Freight, Inc. v. O'Connor & Hannan*, 494 N.W.2d 261, 268 (Minn. 1992); *Ulrich v. City of Crosby*, 848 F. Supp. 861, 867 (D. Minn. 1994).)

Having conceded these key elements of Judge Noel's analysis, Plaintiffs nonetheless argue that Judge Noel "overlook[ed] specific, factual allegations" that purportedly meet the "deliberate disregard for a high probability of injury" standard. He did no such thing.

B. Judge Noel Correctly Concluded that Plaintiffs Failed to Allege Facts Showing Defendants' Deliberate Disregard for a High Probability of Injury.

Plaintiffs first assert that Judge Noel overlooked their allegations "concerning Defendants' knowledge of Bair Hugger contamination." (Pl. Obj. at 10.) But Judge Noel not only *did not* overlook those allegations, he expressly *assumed* Defendants' knowledge on this point. He began his analysis by accepting as true Plaintiffs' allegation that Bair Hugger devices are contaminated with bacteria: "The Court, in accepting as true for the purposes of analyzing whether Plaintiffs have stated a claim for punitive damages as a matter of law, assumes to be true that the Bair Hugger devices were contaminated with bacteria." (ECF No. 629 at 16.) For purposes of his analysis, Judge Noel also expressly assumed that "Defendants had *knowledge* of the presence of *bacteria* in the Bair Hugger device." (*Id.* (emphasis in original).) Judge Noel was willing to make this assumption (which, as he noted, was not required under *Twombly-Iqbal*) because he was focused on the question that mattered most: what alleged facts support a reasonable inference that

Defendants knew the presence of bacteria in Bair Hugger devices would present a high probability of injury to patients? (*Id.*)

Next, Plaintiffs argue that Judge Noel overlooked allegations from which Defendants' knowledge of "an increased risk of surgical site infections" could be reasonably inferred. They cite several allegations relating to Defendants' use of the M20 filter media in the Bair Hugger Model 750 rather than the allegedly more efficient M10 filter media used in the Model 505. (Pl. Obj. at 5, citing proposed SAC ¶¶ 210, 211, 234.) Judge Noel did not overlook these allegations, but instead addressed them head on, concluding: "The arguments that Defendants secretly reduced the Bair Hugger filtration efficiency . . . does not allege factual content that allows the Court to draw a reasonable inference that Defendants are liable for knowing of or intentionally disregarding facts that make injury highly probable." (Order at 17.)

Plaintiffs cite several other allegations relating to Defendants' decision not to undertake an additional contamination study that was proposed by one of its consultants. (Pl. Obj. at 5, citing proposed SAC ¶¶ 258, 259, 260.) Again, Judge Noel addressed these allegations directly: "Plaintiffs have provided no factual support for the proposition that Defendants willfully suppressed potential harmful testing. Even if the Court were bound to assume this to be true, . . . [s]uppression of potentially harmful testing or failing to warn of bacterial contamination, does not permit the reasonable inference that Defendants were deliberately indifferent to an increased risk of surgical site infections." (Order at 17.) He concluded that "[t]he arguments that Defendants . . . failed to conduct a contamination

study” do not support a reasonable inference that Defendants are liable for “knowing of or intentionally disregarding facts that make injury highly probable.” (*Id.*)

Finally, Judge Noel did not ignore the various studies cited by Plaintiffs. He considered the studies and noted that each and every one of them “disclaims any direct correlation between the presence of bacteria and an increase in the risk of surgical site infections.” (*Id.* at 16.)

Publication	Language Disclaiming Conclusion that Bair Hugger Warming Blanket Increases Risk
Albrecht M et al., Forced-air warming: a source of airborne contamination in the operating room? <i>Orthopedic Rev.</i> 2009; 1(2):e28 (PX29 ¹)	“[T]he present study did not evaluate the link between forced air warming and surgical site infection rates ... ”
Albrecht M et al., Forced-air warming blowers: An evaluation of filtration adequacy and airborne contamination emissions in the operating room. <i>Am J Infect Control</i> 2010; 39:321-28 (PX30)	“[O]ur findings do not establish a direct link between forced air warming and increased surgical site infection rates ...”
McGovern PD et al., Forced-air warming and ultra-clean ventilation do not mix. <i>J Bone & Joint Surg-Br.</i> 2011; 93-B(11):1537-44 (PX32)	“This study does not establish a causal basis for this association [the patient warming device and the risks of surgical site infections in the study].”
Legg A et al., Do forced air patient-warming devices disrupt unidirectional downward airflow? <i>J Bone & Joint Surg-Br.</i> 2012; 94-B:254-6 (PX34)	“Because of the nature of our experiment we are unable to conclude that the use of the forced air warming device ... would actually lead to an increased risk of surgical site infection. ”

¹ References to “PX” are to Plaintiffs’ exhibits submitted in support of their motion for leave to amend their Complaints to add a claim for punitive damages (ECF 307).

Dasari KR et al., Effect of forced air warming on the performance of operating theatre laminar flow ventilation. <i>Anaesthesia</i> 2012; 67:244-49 (PX35)	“Another limitation of our study is that the definitive effects of this excess heat on clinical outcomes is presently unknown. ”
Legg A et al., Forced-air patient warming blankets disrupt unidirectional airflow. <i>Bone Joint J.</i> 2013 Mar; 95-B(3):407-10 (PX36)	“ This study does not show that forced-air warming increases the risk of infection ... ”
Reed M et al., Forced-air warming design: evaluation of intake filtration, internal microbial buildup, and airborne-contamination emissions. <i>AANA J.</i> 2013 Aug; 81(4):275-80 (PX38)	“Last, we did not track hospital infections, nor did we study the association between FAW [forced-air warming] contamination generation/emission and hospital infection rates ... ”
Belani K et al., Patient warming excess heat: The effects on orthopedic operating room ventilation performance. <i>Anesthesia & Analgesia</i> 2012 (prepublication on-line) 2013; 117(2):406-411 (PX37)	“Thus, we are unsure of the exact degree of ventilation disruption that might occur in a working OR during orthopedic surgery... future research is warranted to characterize the clinical conditions under which forced air warming excess heat results in ventilation disruption during surgery.”

Plaintiffs nonetheless argue that the studies should have put Defendants on notice that the Bair Hugger system *does* cause surgical site infections. (Pl. Obj. at 9.) But Plaintiffs offer no legal or logical support for the novel proposition that the Court should infer that a company understands scientific studies to mean the opposite of what they say. That is the Plaintiffs’ case in a nutshell.

II. IN THE ALTERNATIVE, JUDGE NOEL’S ORDER SHOULD BE AFFIRMED BECAUSE PLAINTIFFS FAILED TO MEET THEIR EVIDENTIARY BURDEN UNDER MINN. STAT. § 549.191.

In the alternative, Judge Noel’s order should be affirmed because Plaintiffs failed to meet their evidentiary burden under Minn. Stat. § 549.191. As Defendants argued to Judge Noel, the Minnesota statute and plain language of Rule 15(a)(2) can peacefully coexist, as courts in this District had previously concluded up until now.

A. Minn. Stat. § 549.191 Does Not “Directly Collide” with Rule 15(a)(2).

Under Justice Scalia’s approach in *Shady Grove*, Rule 15 clearly governs Plaintiffs’ motion. But Scalia spoke for four Justices, not the majority. Justice Stevens’ concurrence, following *Hanna v. Plumer*, 380 U.S. 460 (1965), framed the question more narrowly as to whether there is a “direct collision” between the federal and state rules, or whether “both can operate.” *Shady Grove Orthopedic Assocs. P.A. v. Allstate Ins. Co.*, 559 U.S. 393, 422 (2010).

If Justice Stevens’ concurrence is controlling, and most courts have concluded that it is,² then *Shady Grove* does not represent a significant change in Supreme Court precedent, but rather a continuation of *Hanna*’s “direct collision” test. Before *Shady Grove*, two courts in this District had applied *Hanna*’s “direct collision” test and concluded that the federal pleading rules can peacefully coexist with Minn. Stat. § 549.191. *Kuehn v.*

² See, e.g., *Davenport v. Charter Comms., LLC*, 35 F. Supp. 3d 1040, 1050 (E.D. Mo. 2014) (collecting cases and quoting *McKinney v. Bayer Corp.*, 744 F. Supp. 2d 733, 747 (N.D. Ohio 2010) (“Because Justice Stevens’ concurring opinion would permit some state law provisions addressing class actions – whereas Justice Scalia’s opinion . . . would broadly prohibit any state law that conflicted with Rule 23 – Justice Stevens’ opinion is the narrowest and, thus, controlling opinion.”)).

Shelcore, Inc. 686 F. Supp. 233, 234 (D. Minn. 1988) (Rule 8); *Security Savs. Bank v. Green Tree Acceptance, Inc.*, No. 3-89-28, 1990 WL 36142, at *1-2 (D. Minn. Mar. 22, 1990) (Rule 15). In *Kuehn*, Judge Devitt explained:

Federal Rule 8 is a general pleading rule; its only potential conflict with § 549.191 is that it does not prohibit pleading punitive damages without leave of court. Federal Rule 8 does not, however, directly conflict with § 549.191. Both can be given simultaneous effect.

Federal Rule 8 is concerned with simplifying pleading requirements; *Clausen & Sons, Inc. v. Theo. Hamm Brewing Co.*, 395 F.2d 388, 390 (8th Cir.1968); *Johnson v. Occidental Life Ins. Co.*, 1 F.R.D. 554, 555 (D. Minn. 1941); § 549.191, however, is aimed at deterring past abusive pleading practices regarding punitive damages in order to address a perceived insurance crisis. Note, Introduction to Minnesota's Tort Reform Act, 13 Wm. Mitchell L. Rev. 277, 294–95 (1987); Cole, Tort Reform – Toward Moderation, 13 Wm. Mitchell L. Rev. 335, 339 (1987).

The policies of § 549.191 make it “an ‘integral’ part” of the Tort Reform Act and Rule 8 “does not replace such policy determinations.” The two can peacefully co-exist, “each controlling its own intended sphere of coverage without conflict.” *Walker*, 466 U.S. at 752, 100 S. Ct. at 1986. This is evident from the fact that there has been no change in Minnesota Rule of Federal Procedure 8 since passage of § 549.191. Minnesota Rule 8 is virtually identical to Federal Rule 8. “Just as [§ 549.191] and [Minnesota Rule 8] can both apply in state court for their separate purposes, so too [§ 549.191] and [Federal Rule 8] may both apply in federal court in a diversity action.” *Walker* at 752 n.13.

Kuehn, 686 F. Supp. at 234 (final citation partially omitted). Following this same analytical approach, Judge Becker determined that Section 549.191 does not directly conflict with Rule 15. In *Security Savs. Bank*, 1990 WL 36142, at *2, Judge Becker concluded that “[t]here is no direct conflict between Rule 15(a) and section 549.191 Rule 15, Fed. R. Civ. P., does not even attempt to address the issue posed in section 549.191.” Rule 15 can

peacefully coexist with Minn. Stat. § 549.191 because the statute could also coexist with Minnesota Rule 15.01, which “is virtually identical to Federal Rule 15(a).” *Id.*

The plain language of Rule 15(a)(2) also is compatible with Minn. Stat. § 549.191. The Rule provides that the district court should freely give leave to amend “when justice so requires.” “Justice” can and should be read to incorporate Section 549.191’s requirements. As *Kuehn* explains, Section 549.191 represents the Minnesota state legislature’s view that it would be unjust to allow a plaintiff to pursue punitive damages without first “showing the factual basis for the [punitive damages] claim” by submitting “one or more affidavits.”

Similarly, it is well established in the Eighth Circuit that a district court should refuse to grant leave to amend under Rule 15(a) where amendment would cause “unfair prejudice to the opposing party.” *Sanders v. Clemco Indus.*, 823 F.2d 214, 216 (8th Cir. 1987). Defendants will be unfairly prejudiced if they are forced to defend against punitive damages claims in the MDL that they never would have to defend if the same claims had been brought in Minnesota state court.

In his order, Judge Noel concludes that Rule 15 and Minn. Stat. § 549.191 “conflict because the Minnesota procedural rule would not allow for the amendment absent affidavits establishing *prima facie* evidence of deliberate disregard for the rights of safety of others, where the federal rule has no such procedural requirement.” But that is just another way of saying that the two rules speak to the same procedural issue. That is closer to Justice Scalia’s test than Justice Stevens’ test. It misses the distinction between “direct collision,” where the state rule cannot be applied without violating the plain language of

the federal rule, and situations like the one here, where the state rule can be applied without abridging the plain language of the federal rule.

B. Plaintiffs' Evidence Falls Far Short of Clear and Convincing Evidence of a Deliberate Disregard for a High Probability of Injury.

There is insufficient space here to address Plaintiffs' evidentiary proffer in detail, and Defendants therefore refer the Court to Judge Leary's August 18 Order denying Plaintiffs leave to seek punitive damages. Judge Leary's Order thoroughly discusses the evidence submitted by Plaintiffs both individually and collectively, and compares that evidence with other cases (including federal district court cases) that have evaluated motions brought under Minn. Stat. § 549.191. He concludes that Plaintiffs have failed to come forward with clear and convincing evidence, as they must,³ that either Arizant or 3M was deliberately indifferent to a safety risk or of probable surgical site infection. To find otherwise would fly in the face of the same studies on which Plaintiffs rely, which, as shown above, uniformly disclaim a causal relationship between the use of the Bair Hugger system and surgical infections. (Hulse Decl., Ex. A, Ramsey County Order ¶¶ 8-10.)

Moreover, there has never been an FDA recall of the Bair Hugger system related to infection (or otherwise), and no FDA safety communication, warning letter, or other enforcement action related to an infection. (Hulse Decl., Ex. A, Ramsey County Order ¶¶ 27-28.) Even though over 200 million surgeries have been conducted using the Bair Hugger system over more than 25 years, not one doctor has ever reported to 3M or Arizant

³ See Judge Noel's Order at 13, finding no conflict between the substantive punitive damages standard of the forum (Minnesota) and the substantive punitive damages laws of the bellwether states (Wisconsin, Florida, South Carolina, Idaho).

that the Bair Hugger system caused his or her patient to develop a surgical site infection. The facts here are therefore like those in *Healey v. I-Flow LLC*, 853 F. Supp. 2d 868, 881 (D. Minn. 2012), where Judge Keyes denied the motion for leave to allege punitive damages. In *Healey*, as here, the plaintiff submitted no evidence that a physician ever informed the defendant that the defendant's medical device had caused his injury. 853 F. Supp. 2d at 877-81. This litigation is likewise similar to *Mack v. Stryker Corp.*, No. 10-2993 (PAM/JJG), 2012 WL 12896248 (D. Minn. Feb. 28, 2012). There, Judge Graham denied leave to amend where there were no reports from doctors of injuries caused by the use of Stryker's device prior to the plaintiff's surgery. *Id.* at *4. (Hulse Decl., Ex. A, Ramsey County Order ¶ 28).

Indeed, as Judge Leary concluded: "Neither party has identified any case where a court applying Minnesota law has permitted leave to amend to allege punitive damages in similar circumstances: where the defendant's medical device remains the standard of care; its significant benefits to patient health and safety are undisputed; there has been no FDA action or warning; no doctor has complained that the defendant's product caused any injury; and there is no scientific study concluding that the defendant's product causes injuries." (*Id.* ¶ 29.)

CONCLUSION

This Court should overrule Plaintiffs' objection to Judge Noel's order denying Plaintiffs' motion for leave to add a claim for punitive damages. Two alternative bases support Judge Noel's order. As Judge Noel concluded, Plaintiffs' proposed Second Amended Complaint failed to allege facts supporting a reasonable inference that

Defendants were deliberately indifferent to a safety risk or of probable surgical site infections. And if the Court looks at the evidence Plaintiffs offered in support of their allegations, the deficiency is even clearer. As Judge Leary concluded, Plaintiffs' evidence "falls far short" of clear and convincing evidence of punishable misconduct by either of the Defendants.

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Respectfully submitted,

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